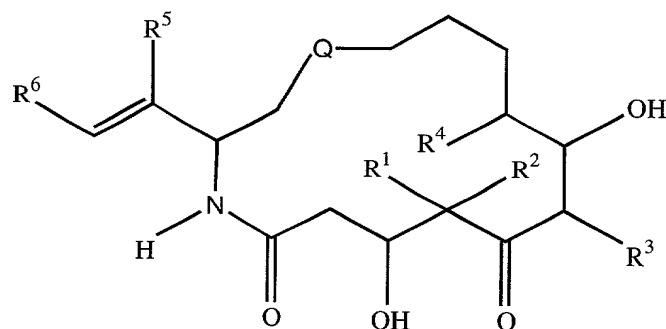


**What is claimed is:**

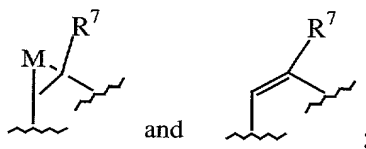
1. A process for formulating, for parenteral administration, an epothilone analog represented by formula I:



I

wherein:

Q is selected from the group consisting of:



M is selected from the group consisting of oxygen, sulfur,  $\text{NR}^8$ , and  $\text{CR}^9\text{R}^{10}$ ;

each  $\text{R}^1$ ,  $\text{R}^2$ ,  $\text{R}^3$ ,  $\text{R}^4$ ,  $\text{R}^5$ ,  $\text{R}^7$ ,  $\text{R}^{11}$ ,  $\text{R}^{12}$ ,  $\text{R}^{13}$ ,  $\text{R}^{14}$  and  $\text{R}^{15}$  is, independently, selected from the group consisting of hydrogen, alkyl, substituted alkyl, aryl, substituted aryl and heterocyclo, and wherein  $\text{R}^1$  and  $\text{R}^2$  are alkyl, they can be joined to form cycloalkyl;

$\text{R}^6$  is selected from the group consisting of hydrogen, alkyl, substituted alkyl, aryl, substituted aryl, cycloalkyl, heterocyclo and substituted heterocyclo;

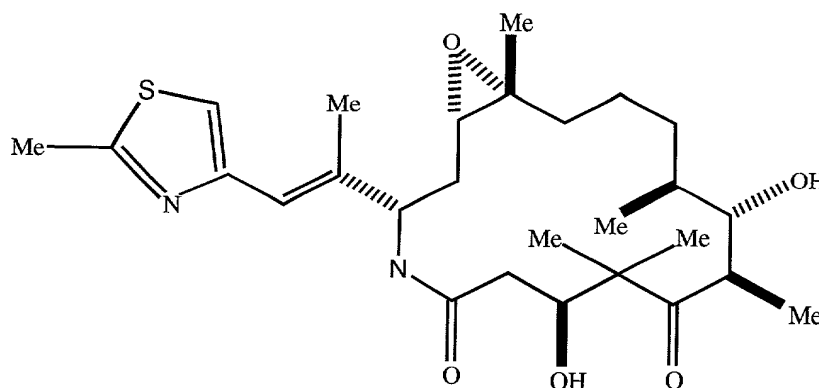
$\text{R}^8$  is selected from the group consisting of hydrogen, alkyl, substituted alkyl,  $\text{R}^{11}\text{C}=\text{O}$ ,  $\text{R}^{12}\text{OC}=\text{O}$  and  $\text{R}^{13}\text{SO}_2$ ; and

each  $\text{R}^9$  and  $\text{R}^{10}$  is, independently, selected from the group consisting of hydrogen, halogen, alkyl, substituted alkyl, aryl, heterocyclo, hydroxy,  $\text{R}^{14}\text{C}=\text{O}$ , and  $\text{R}^{15}\text{OC}=\text{O}$ ;

and any salts, solvates, or hydrates thereof, comprising the following steps carried out under protection from light:

- a) dissolving said epothilone analog in a mixture of at least about 50% by volume tertiary-butanol in water to form a solution;
- b) performing primary drying of said solution at a temperature of from about -10°C to about -40°C under high vacuum of from about 50 millitorr to about 300 millitorr for from about 24 hours to about 96 hours to form a lyophilized product;
- c) performing secondary drying of the resultant lyophilized product at a temperature of from about 10 °C to about 30°C under high vacuum of from about 50 millitorr to about 300 millitorr for from 24 hours to about 96 hours; and
- d) packaging said lyophilized product in a first vial in combination with a second vial containing a sufficient quantity of an equal mixture by volume of a suitable nonionic surfactant and anhydrous ethanol to effect solution thereof.

2. The process of claim 1 wherein said epothilone analog is represented by formula II:



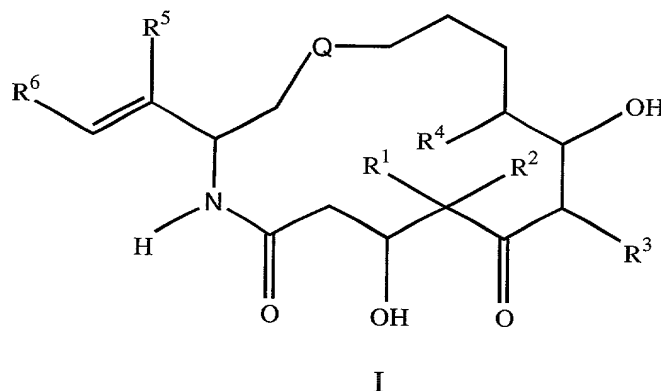
II

3. The process of claim 1 wherein in step a) said analog is first wetted with a mixture of at least about 60% tertiary-butanol in water, and then sufficient water, or a mixture of tertiary-butanol and water, is added thereto so that the resulting solution contains from about 2 mg/mL to about 30 mg/mL of said analog in a mixture of from about 50% to about 80% by volume tertiary-butanol in water.
4. The process of claim 2 wherein in step a) said analog is first wetted with a mixture of at least about 60% tertiary-butanol in water, and then sufficient water, or a

mixture of tertiary-butanol and water, is added thereto so that the resulting solution contains from about 2 mg/mL to about 30 mg/mL of said analog in a mixture of from about 50% to about 80% by volume tertiary-butanol in water.

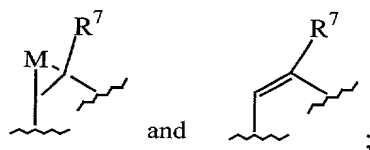
5. The process of claim 3 wherein in step a) said analog is initially wetted with a mixture of from about 60% to about 95% by volume tertiary-butanol in water.
6. The process of claim 4 wherein in step a) said analog is initially wetted with a mixture of from about 60% to about 95% by volume tertiary-butanol in water.
7. The process of claim 1 wherein said primary drying in step b) is carried out at a temperature of about -25°C and a pressure of about 200 millitorr for about 48 hours.
8. The process of claim 2 wherein said primary drying in step b) is carried out at a temperature of about -25°C and a pressure of about 200 millitorr for about 48 hours.
9. The process of claim 1 wherein said secondary drying in step c) is carried out at a temperature of about 25°C and a pressure of about 150 millitorr for about 48 hours.
10. The process of claim 2 wherein said secondary drying in step c) is carried out at a temperature of about 25°C and a pressure of about 150 millitorr for about 48 hours.
11. The process of claim 1 wherein said surfactant is polyethoxylated castor oil.
12. The process of claim 2 wherein said surfactant is polyethoxylated castor oil.
13. The process of claim 11 wherein said second vial contains an amount of said mixture sufficient to form a solution of from about 2 mg/mL to about 4 mg/mL of said analog therein.

14. The process of claim 12 wherein said second vial contains an amount of said mixture sufficient to form a solution of from about 2 mg/mL to about 4 mg/mL of said analog therein.
15. A pharmaceutical preparation comprising, in separate vials, a lyophilized epothilone analog and a quantity of a solvent therefor such that when the contents of said vials are combined, the resulting solution contains from about 2 mg/mL to about 4 mg/mL of said analog, said solvent comprising a mixture of about equal parts by volume of dehydrated ethanol and a suitable nonionic surfactant, said analog being represented by formula I:



wherein:

Q is selected from the group consisting of



M is selected from the group consisting of oxygen, sulfur,  $\text{NR}^8$ , and  $\text{CR}^9\text{R}^{10}$ ; each  $\text{R}^1$ ,  $\text{R}^2$ ,  $\text{R}^3$ ,  $\text{R}^4$ ,  $\text{R}^5$ ,  $\text{R}^7$ ,  $\text{R}^{11}$ ,  $\text{R}^{12}$ ,  $\text{R}^{13}$ ,  $\text{R}^{14}$  and  $\text{R}^{15}$  is, independently, selected from the group consisting of hydrogen, alkyl, substituted alkyl, aryl, substituted aryl and heterocyclo, and wherein  $\text{R}^1$  and  $\text{R}^2$  are alkyl, they can be joined to form cycloalkyl;

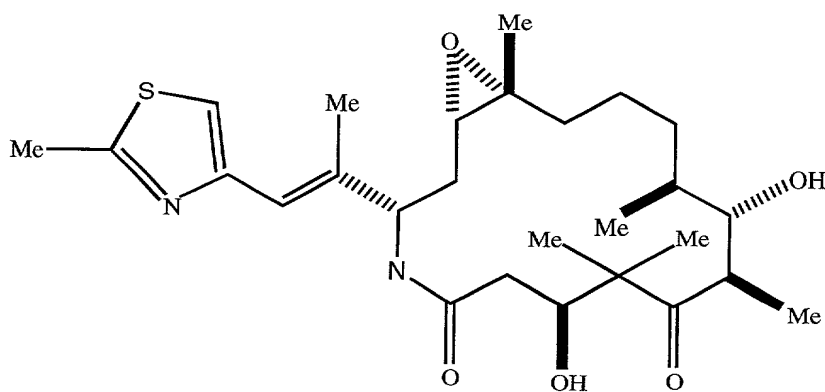
$\text{R}^6$  is selected from the group consisting of hydrogen, alkyl, substituted alkyl, aryl, substituted aryl, cycloalkyl, heterocyclo and substituted heterocyclo;

$R^8$  is selected from the group consisting of hydrogen, alkyl, substituted alkyl,  $R^{11}C=O$ ,  $R^{12}OC=O$  and  $R^{13}SO_2$ ; and

each  $R^9$  and  $R^{10}$  is, independently, selected from the group consisting of hydrogen, halogen, alkyl, substituted alkyl, aryl, heterocyclo, hydroxy,  $R^{14}C=O$ , and  $R^{15}OC=O$ ;

and any salts, solvates, or hydrates thereof.

16. The pharmaceutical preparation of claim 15 wherein said epothilone analog is represented by formula II:

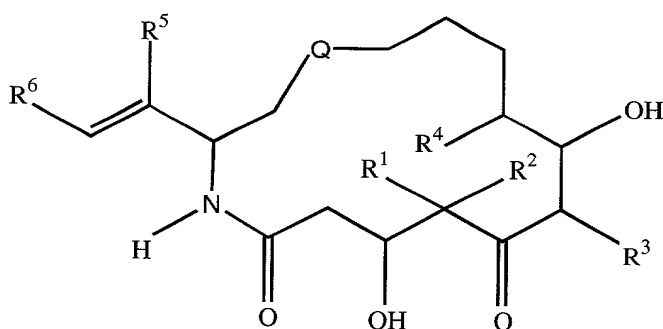


II

17. The pharmaceutical preparation of claim 16 wherein said nonionic surfactant is polyethoxylated castor oil.

18. A process for forming a pharmaceutical composition for parenteral administration comprising mixing the contents of the vials of the pharmaceutical preparation of any of claim 15 to effect solution of said lyophilized epothilone analog and diluting the resultant solution with a quantity of a suitable parenteral diluent such that the concentration of said analog therein will be from about 0.1 mg/mL to about 0.9 mg/mL.

19. A process for forming a pharmaceutical composition for parenteral administration comprising mixing the contents of the vials of the pharmaceutical preparation of any of claim 16 to effect solution of said lyophilized epothilone analog and diluting the resultant solution with a quantity of a suitable parenteral diluent such that the concentration of said analog therein will be from about 0.1 mg/mL to about 0.9 mg/mL.
20. A process for forming a pharmaceutical composition for parenteral administration comprising mixing the contents of the vials of the pharmaceutical preparation of any of claim 17 to effect solution of said lyophilized epothilone analog and diluting the resultant solution with a quantity of a suitable parenteral diluent such that the concentration of said analog therein will be from about 0.1 mg/mL to about 0.9 mg/mL.
21. The process of claim 18 wherein said diluent is Lactated Ringer's Injection.
22. The process of claim 19 wherein said diluent is Lactated Ringer's Injection.
23. The process of claim 20 wherein said diluent is Lactated Ringer's Injection.
24. A process for treating a patient in need of treatment with an epothilone analog

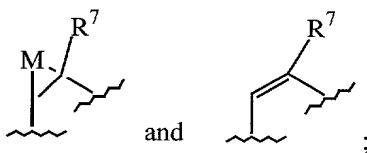


represented formula I:

I

wherein:

Q is selected from the group consisting of



M is selected from the group consisting of oxygen, sulfur, NR<sup>8</sup>, and CR<sup>9</sup>R<sup>10</sup>; each R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup>, R<sup>4</sup>, R<sup>5</sup>, R<sup>7</sup>, R<sup>11</sup>, R<sup>12</sup>, R<sup>13</sup>, R<sup>14</sup> and R<sup>15</sup> is, independently, selected from the group consisting of hydrogen, alkyl, substituted alkyl, aryl, substituted aryl and heterocyclo, and wherein R<sup>1</sup> and R<sup>2</sup> are alkyl, they can be joined to form a cycloalkyl;

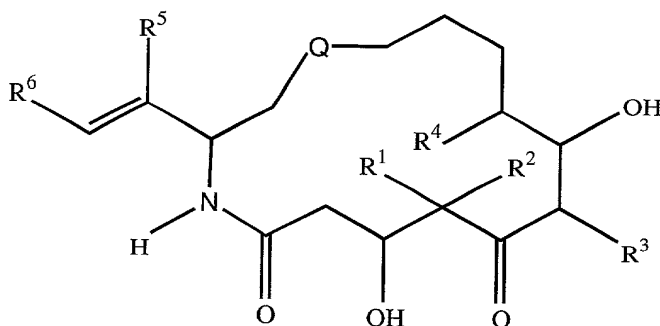
R<sup>6</sup> is selected from the group consisting of hydrogen, alkyl, substituted alkyl, aryl, substituted aryl, cycloalkyl, heterocyclo and substituted heterocyclo;

R<sup>8</sup> is selected from the group consisting of hydrogen, alkyl, substituted alkyl, R<sup>11</sup>C=O, R<sup>12</sup>OC=O and R<sup>13</sup>SO<sub>2</sub>; and

each R<sup>9</sup> and R<sup>10</sup> is, independently, selected from the group consisting of hydrogen, halogen, alkyl, substituted alkyl, aryl, heterocyclo, hydroxy, R<sup>14</sup>C=O, and R<sup>15</sup>OC=O;

and any salts, solvates, or hydrates thereof, comprising administering to said patient, by intravenous injection, an effective amount of a pharmaceutical composition of claim 18.

25. A process for treating a patient in need of treatment with an epothilone analog

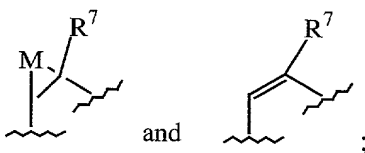


represented formula I:

I

wherein:

Q is selected from the group consisting of



M is selected from the group consisting of oxygen, sulfur, NR<sup>8</sup>, and CR<sup>9</sup>R<sup>10</sup>; each R<sup>1</sup>, R<sup>2</sup>, R<sup>3</sup>, R<sup>4</sup>, R<sup>5</sup>, R<sup>7</sup>, R<sup>11</sup>, R<sup>12</sup>, R<sup>13</sup>, R<sup>14</sup> and R<sup>15</sup> is, independently, selected from the group consisting of hydrogen, alkyl, substituted alkyl, aryl, substituted aryl and heterocyclo, and wherein R<sup>1</sup> and R<sup>2</sup> are alkyl, they can be joined to form a cycloalkyl;

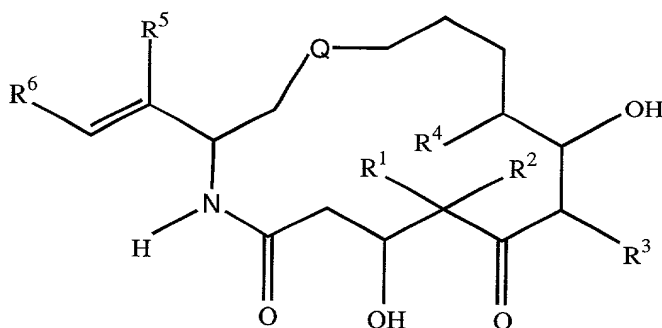
R<sup>6</sup> is selected from the group consisting of hydrogen, alkyl, substituted alkyl, aryl, substituted aryl, cycloalkyl, heterocyclo and substituted heterocyclo;

R<sup>8</sup> is selected from the group consisting of hydrogen, alkyl, substituted alkyl, R<sup>11</sup>C=O, R<sup>12</sup>OC=O and R<sup>13</sup>SO<sub>2</sub>; and

each R<sup>9</sup> and R<sup>10</sup> is, independently, selected from the group consisting of hydrogen, halogen, alkyl, substituted alkyl, aryl, heterocyclo, hydroxy, R<sup>14</sup>C=O, and R<sup>15</sup>OC=O;

and any salts, solvates, or hydrates thereof, comprising administering to said patient, by intravenous injection, an effective amount of a pharmaceutical composition of claim 19.

26. A process for treating a patient in need of treatment with an epothilone analog



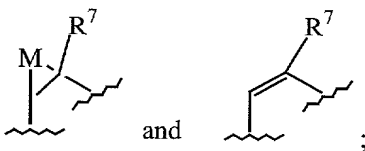
represented formula I:

I

wherein:



Q is selected from the group consisting of



M is selected from the group consisting of oxygen, sulfur,  $\text{NR}^8$ , and  $\text{CR}^9\text{R}^{10}$ ; each  $\text{R}^1$ ,  $\text{R}^2$ ,  $\text{R}^3$ ,  $\text{R}^4$ ,  $\text{R}^5$ ,  $\text{R}^7$ ,  $\text{R}^{11}$ ,  $\text{R}^{12}$ ,  $\text{R}^{13}$ ,  $\text{R}^{14}$  and  $\text{R}^{15}$  is, independently, selected from the group consisting of hydrogen, alkyl, substituted alkyl, aryl, substituted aryl and heterocyclo, and wherein  $\text{R}^1$  and  $\text{R}^2$  are alkyl, they can be joined to form a cycloalkyl;

$\text{R}^6$  is selected from the group consisting of hydrogen, alkyl, substituted alkyl, aryl, substituted aryl, cycloalkyl, heterocyclo and substituted heterocyclo;

$\text{R}^8$  is selected from the group consisting of hydrogen, alkyl, substituted alkyl,  $\text{R}^{11}\text{C}=\text{O}$ ,  $\text{R}^{12}\text{OC}=\text{O}$  and  $\text{R}^{13}\text{SO}_2$ ; and

each  $\text{R}^9$  and  $\text{R}^{10}$  is, independently, selected from the group consisting of hydrogen, halogen, alkyl, substituted alkyl, aryl, heterocyclo, hydroxy,  $\text{R}^{14}\text{C}=\text{O}$ , and  $\text{R}^{15}\text{OC}=\text{O}$ ;

and any salts, solvates, or hydrates thereof, comprising administering to said patient, by intravenous injection, an effective amount of a pharmaceutical composition of claim 20.

27. The process of claim 24 wherein said diluent is Lactated Ringer's Injection.
28. The process of claim 25 wherein said diluent is Lactated Ringer's Injection.
29. The process of claim 26 wherein said diluent is Lactated Ringer's Injection.